REMARKS

Claims 18-28, 31-35, and 39-40 are pending in this application. Claims 18-28, 31-32, 34-35 and 39-40 were variously rejected under 35 U.S.C. § 112, second paragraph. Claims 31-33 were rejected under 35 U.S.C. § 102(b). Claims 18-28, 31-35 and 39-40 were variously rejected under 35 U.S.C. § 103.

By this amendment, claim 31 has been amended without prejudice or disclaimer of any previously claimed subject matter. The amendment is made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejection under 35 U.S.C. §112, second paragraph

Claims 18-28, 31-32, 34-35 and 39-40 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

In finding claims 18 and 19 indefinite because of the phrase "non-fibrous solid carrier comprising at least 15% (w/w) of an edible carbohydrate polymer," the Examiner states that "one cannot determine if the term "non-fibrous carriers" refers to edible digestible non-fibrous carriers or non-digestible non-fibrous carriers." Office Action, section 6. The claims state that the carbohydrate polymer is edible and the specification states that the "polymer should be chosen so

that it is edible by the animal for whom the feed is intended, and preferably digestible as well." Page 6, lines 29-30. Applicants respectfully point out that as claims 18 and 19 do not recite "digestible" or "non-digestible," these terms should not be read into the claims and one does not need to determine whether or not the non-fibrous carrier is digestible.

The Examiner also states that "starch can be a non-fibrous carrier as well as an edible carbohydrate polymer" and in such an instance, the phrase in question is "equivalent to "starch comprising at least 15% of starch"" (Office Action, section 6). Applicants respectfully submit that such a scenario does not render the claim indefinite. If the carrier is 100% starch, then it fulfills the requirement of comprising at least 15% starch. The specification provides for embodiments in which the edible carbohydrate polymer content of the solid carrier varies from at least 15% (w/w) to about 100% (w/w). See, for example, page 7, lines 15-24.

Accordingly, Applicants respectfully submit that claims 18 and 19 are sufficiently definite when considered in view of the specification and the understanding of those of skill in the art.

The Examiner asserts that claim 31 is indefinite in the recitation of "both a granulate according to (a) and a phytase-containing granulate according to (b)." Office Action, section 7. Although Applicants believe the claim is sufficiently definite when considered in view of the specification and the understanding of those of skill in the art, claim 31 has herein been amended in the interest of expediting prosecution of this case. Accordingly, Applicants respectfully submit that this rejection of claim 31 is moot.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. §102(b)

Claims 31-33 were rejected under 35 U.S.C. §102(b) as allegedly unpatentable over Nielsen et al. (WO 95/28850, "Nielsen"). Applicants respectfully traverse this rejection.

Claim 31 is directed to a composition comprising a phytase-containing granulate with an activity of at least 6000 FTU/g. The Examiner asserts that Nielsen teaches a phytase-containing granulate comprising 10,000 FTU/g of total composition. As addressed below with the 35. U.S.C. §103 rejection, Applicants respectfully submit that Nielsen does not teach a phytase-containing granulate with 10,000 FTU/g nor with an activity of at least 6000 FTU/g. Further Nielsen does not teach a phytase-containing granulate with an activity of at least 6000 FTU/g and also containing a carrier comprising at least 15% (w/w) of an edible polymer, as in amended claim 31.

Accordingly, Applicants submit that Nielsen does not anticipate the claimed invention.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b).

Rejection under 35 U.S.C. §103

Claims 18-21, 24-28 and 31-35 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Nielsen, *et al.* (WO 95/28850, "Nielsen") in view of Ghani (U.S. Pat. No. 6,120,811). Claims 22 and 23 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Nielsen in view of Ghani and further in view of Markussen et al. (U.S. Pat. No. 4,106,991, "Markussen"). Claims 39 and 40 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Nielsen in view of Ghani and Markussen and further in view of Haarasilta (GB 2-139868A). Applicants respectfully traverse this ground for rejection.

A *prima facie* case of obviousness requires that three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488,

20USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143. If any one of these three criteria is not met, a *prima facie* case of obviousness has not been established. As presented below, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

The present invention provides methods for producing liquid and granulate compositions containing high phytase activity. Applicants have discovered microorganism culture conditions and filtration steps that result in an aqueous liquid with a phytase activity concentration of 14,000 FTU per gram of aqueous liquid or greater. Granulates with more concentrated phytase activity were found to be much more stable than granulates with less concentrated phytase activity. Making granules using a high activity phytase liquid resulted in increased pelleting stability compared to granules made with lower phytase activity liquid. See, for example, specification page 3, lines 26-31, and Example 5.

Specifically, the claimed invention is directed to a phytase-containing granulate prepared by a process comprising providing a solid carrier comprising at least 15% of an edible carbohydrate polymer; providing an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid; and mixing the solid carrier and the aqueous liquid to form a granulate having a phytase activity of at least 6000 FTU per gram. The claimed invention is also directed to a granulate having a phytase activity of at least 6000 FTU per gram, where the granulate includes dried granules formed from an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid and a solid carrier which comprises at least 15% of an edible carbohydrate polymer. In the claimed invention, the solid carrier is non-fibrous.

Nielsen is directed to a method for improving the solubility of vegetable proteins by treating a vegetable protein source with a phytase alone or in conjunction with a proteolytic enzyme. Nielsen describes an animal feed additive, containing one or more phytase enzymes and one or more proteolytic enzymes, that may be in the form of a granulated enzyme product or in the form of a liquid composition. Nielsen, page 10, lines 8-24. As noted by the Examiner, Nielsen does not teach

a phytase-containing granulate comprising an edible carbohydrate polymer. Nielsen states ranges of phytase activity that are contemplated for the animal feed additive (200 to 50,000 FYT/g; 500 to 10,000 FYT/g; 2000 to 6000 FYT/g) although does not mention whether these ranges apply to a granulate or liquid enzyme product. Nielsen, page 11, line 27, to page 12, line 2. Despite stating such phytase activity ranges, Nielsen does not demonstrate any granulate or liquid preparations with the high phytase activity concentrations as presently claimed. Nor does Nielsen teach, suggest or provide any information on how to obtain granulate or liquid preparations with the claimed phytase activity.

In the working examples of Nielsen, Phytase Novo™ from Novo Nordisk ranging in activity from 5000 FYT/g to 7370 FYT/g is the source of phytase enzyme. Phytase Novo™ is a feed additive product that was available in two forms: a coated granulate product at 2500 FYT/g and a liquid product at 5000 FYT/g (see product sheets from 1994 and 1995 attached herewith as Appendix A). Although Nielsen does not specifically state whether the granulate or liquid Phytase Novo™ product was used, the phytase activity described in the working examples makes it highly likely that Nielsen used the liquid product. Thus, Nielsen does not specifically describe a phytase-containing granulate composition with a phytase activity of at least 6000 FTU per gram. Nor does Nielsen specifically describe an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid.

The combination of the primary reference of Nielsen with the secondary reference of Ghani does nothing to cure these important defects. Ghani describes microgranules containing an enzyme, a carrier such as soy flour, soy grits, corn flour, etc., and other components. Ghani does not teach an enzyme granulate containing a phytase, nor a granulate containing a phytase activity of at least 6000 FTU per gram, much less a granulate formed by the use of an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid.

Applicants respectfully submit that neither Nielsen nor Ghani, alone or in combination, teaches or suggests all the limitations of the claimed invention. Neither reference describes or suggests a phytase-containing granulate having a phytase activity of at least 6000 FTU per gram of granulate. Neither reference describes or suggests the use of a phytase-containing aqueous liquid of at least 14,000 FTU phytase per gram of liquid in the preparation of a granulate having a phytase activity of at least 6000 FTU per gram of granulate. Thus, the combination of Nielsen and Ghani do not teach or suggest the claimed invention. Given the silence in the cited references on required elements of the claims, the cited references cannot render the claims obvious.

In addition, nothing in Nielsen or Ghani teaches how to obtain liquid or granulate compositions with high phytase activity. Accordingly, Applicants respectfully submit that the teachings of the references do not provide one skilled in the art with a reasonable expectation of success.

Further, nothing in Nielsen or Ghani describes the importance of creating compositions with high phytase activity. Thus, Applicants respectfully submit that there is no suggestion or motivation in Nielsen and/or Ghani to modify the teachings therein to arrive at the claimed invention.

Thus, Applicants respectfully submit that a *prima facie* case of obviousness based on Nielsen in view of Ghani has not been established.

The secondary reference Markussen describes derivatized cellulose in enzyme granulates but does not describe phytase-containing granulates. Markussen does not supply what is missing from the primary reference, Nielsen, or from the combination of Nielsen and Ghani. The combinations of Nielsen and the secondary references Ghani and Markussen do not teach or suggest the claimed invention, thus do not render the claimed invention obvious.

The secondary reference Haarasilta describes granulated cattle fodder with soya bean oil but does not describe phytase-containing granulates. Haarasilta does not supply what is missing from the primary reference, Nielsen, or from the combination of Nielsen, Ghani and Markussen. The combinations of Nielsen and the secondary references Ghani, Markussen and Haarasilta do not teach or suggest the claimed invention, thus do not render the claimed invention obvious.

None of the references, either alone or in combination, describes or suggests a phytase-containing granulate composition with a phytase activity of at least 6000 FTU per gram nor the use of a phytase-containing aqueous liquid of at least 14,000 FTU phytase per gram of liquid in the preparation of a granulate having a phytase activity of at least 6000 FTU per gram of granulate. Given the silence in the cited references on required elements of the claims, the cited references cannot render the claims obvious.

Further, Applicants respectfully submit that the teachings of the references do not provide one skilled in the art with a reasonable expectation of success and that there in no suggestion in the art or in these references to modify their teachings to arrive at the claimed invention.

In sum, the cited references do not support *prima facie* obviousness with regard to the claimed invention. Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

Rejection under obviousness-type double patenting

Claims 18-23, 31-35 and 39-40 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 7-16 and 22 of U.S. Pat. No. 6,500,426 (Barendse et al.). Applicants respectfully traverse this ground for rejection.

Applicants respectfully point out that both the present application and U.S. Pat. No. 6,500,426 were filed on the same day, June 4, 1998, and both claim priority to U.S. Provisional Patent Application No. 60/048,611 and European Patent Application No. EP 97201641.4, both filed on June 4, 1997. Accordingly, U.S. Pat. No. 6,500,426 is not a properly cited reference against the present application.

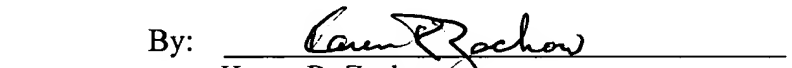
Applicants respectfully request reconsideration and withdrawal of the rejections under obviousness-type double patenting.

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 251502008600. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: August 8, 2003 By: 

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APPENDIX A

Phytase Novo

Application

Phytase Novo is used for improvement of the overall utilization of the nutritional components in feeds for poultry, pigs and other mono-gastric animals. Phytase Novo is able to degrade phytates and thereby increase the availability of phosphorous and other nutritional components in the animal feed.

Description

Phytase Novo is a newly developed enzyme preparation and for its manufacture recombinant DNA technology has been used. The genetic coding for Phytase Novo has been transferred from a donor organism of the *Aspergillus* family to the host organism, *Aspergillus oryzae*.

Specification

Appearance

Phytase Novo is available as a coated granulate (CT), light brown in colour, and as a brown aqueous liquid (L). The products are designed to be compatible with other feed components. The granulate particle size averages 500-600 µm, and as a non-dusty product, it offers considerable advantages compared to powdered enzymes.

Activity

The products typically contain the following enzyme activity:

Activity	Phytase Novo CT	Phytase Novo L
Phytase	2500 FYT/g*	5000 FYT/g*

*Declared minimum activity

Detailed description of Novo Nordisk's method of analysis is available on request.

Dosages

The actual dosages may depend on feed composition, desired effect on feed components and pelleting conditions. General recommended dosages are:

Phytase Novo CT: 0.10 - 0.30 kg/ton of feed, mixed into the feed before any final pelleting of the feed.

Phytase Novo L: 0.05 - 0.15 kg/ton of feed, sprayed on the feed pellets after cooling and dedusting.

Standard Packing

Phytase Novo CT: Fibre drums containing 40 kg.

Phytase Novo L: Plastic jerry cans containing 30 kg.

Storage

Storage stability of Phytase Novo is dependent on storage temperature. Stored at 5°C, the declared activity is maintained for at least one year (two years for Phytase Novo CT). Stored at 25°C, the declared activity is maintained for at least 3 months (12 months for Phytase Novo CT). Prolonged storage at temperatures above 30°C should be avoided.

Safety Aspects

Product safety

Phytase Novo is produced according to the FCC recommendations, supplemented with maximum limits of 5×10^4/g for total viable count and 10^2/g for moulds.

Phytase Novo is free of salmonella bacteria.

Handling precautions

Phytase Novo is formulated in a way that gives the highest degree of safety during handling and the product can safely and easily be incorporated into animal feed formulations.

Use normal handling precautions against direct contact or inhalation of incidental dust. In case of spillage or contact with skin or eyes, rinse promptly with water.

Separate Novo Nordisk leaflets with handling precautions are available on request.

Technical Service

Novo Nordisk's experienced industrial application groups in our worldwide network of branch offices and subsidiaries will be pleased to assist you with further information on the properties and optimum use of Phytase Novo, possibly in combination with Bio-Feed® products.

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